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10/510,500	03/07/2005	John P. Wikswo	14506-44191	9498
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MORRIS MANNING MARTIN LLP			RIGGS II, LARRY D	
3343 PEACHTREE ROAD, NE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,500	Applicant(s) WIKSWO ET AL.
	Examiner LARRY D. RIGGS II	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 June 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4,6,8-10,13,14,28,31,33-37,48,51 and 53-56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 15 September 2008
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,3,5,7,11,12,15-27,29,30,32,38-47,49,50,52 and 57-65.

DETAILED ACTION

Status of Claims

Claims 1-65 are pending. Claims 2, 3, 5, 7, 11, 12, 15-27, 29, 30, 32, 38-47, 49, 50, 52 and 57-65 are withdrawn. Claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 are under consideration.

Withdrawn Rejections/Objections

The objection of the disclosure in the Office action mailed 19 March 2008 is withdrawn in view of the amendments filed 19 June 2008.

The objection to claims 1, 8, 14, 28 and 48, in the Office action mailed 19 March 2008 is withdrawn in view of the amendments filed 19 June 2008.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration, filed 19 June 2008. On the bottom of page 4, "Nashville", "Tennessee", an address and a zip code have been crossed out and "San Jose", "California" with a second zip code has been written in without being dated and initialed. See 37 CFR 1.52(c).

Specification

The amendment filed 19 June 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

"In one embodiment, a confidence level is used to control the iterative process of refinement of the agent classification...when reaching a threshold value, then the iterative process is stopped". The disclosure previously did not provide matter to define what controls the iterative process and subsequently what stops the iteration of steps. Confidence levels and threshold are disclosed, (page 73, second and third paragraphs; page 74, lines 13-14), however they are not provided in terms of controlling or stopping the iterative process. This amended paragraph from page 72, lines 9-21 adds a negative limitation to the disclosure and is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

This rejection is maintained and reiterated in part from the previous office action, mailed 19 March 2008.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "iteratively repeating steps d)-g) until the agent is discriminated" in line 1 of step h). The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to when repeating steps d)-g) would suffice in discrimination of said agent.

Claim 28 recites the limitation "iteratively repeating steps e)-h) until a plurality of classes for the reagent is separated with a desired corresponding confidence level" in lines 1-2 of step i). The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to when repeating steps e)-h) would suffice with a desired corresponding confidence level.

Claim 48 recites the limitation "iteratively repeating steps f)-i) until a class for the agent with a desired robustness factor is obtained" in lines 1-2 of step j). The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as to when repeating steps f)-i) would suffice with a desired robustness factor being obtained.

Response to Arguments

Applicant's arguments filed 19 June 2008 have been fully considered but they are not persuasive.

Applicants argue that by amending the specification to provide an embodiment to explain that a confidence level is used to control and stop the iterative process, and that one skilled in the art would know to use confidence levels to control the invention.

Likewise, applicants argue that a confidence level of about 90% corresponds to a desired corresponding confidence level, (applicant's arguments, page 17) and that a definition of a desired robustness factor is provided in the disclosure, (page 74, lines 18-31 and figure 24).

Applicant's arguments are not persuasive.

The amended specification, mailed 19 June 2008, is not entered. The disclosure previously did not provide matter to define what controls the iterative process and subsequently what stops the iteration of steps. Confidence levels and threshold are disclosed, (page 73, second and third paragraphs; page 74, lines 13-14), however they are not provided in terms of controlling or stopping the iterative process. Thus the added negative limitation of using a confidence level as the means for controlling and stopping the iterative process is moot. There are no indications to what suffices in discriminating an agent, what suffices in a desired confidence level and what suffices in a desired robustness factor. For example, the specification provides "additional subsequent steps that follow the same procedures, with specific feature extraction and classification methods...can be repeated until desired results are obtained, for example, when a desired robustness factor is obtained", (page 74, lines 28-31). Equating desired results to a desired robustness factor does not indicate what suffices as a desired robustness factor to stop the iterative process. Confidence levels, thresholds and factors are tools known in the art, however, one skilled in the art would not know what limitations to place on such tools with the current indefinite claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a method of A method for discriminating an agent, comprising the steps of: (a) constructing a decision tree having a plurality of branches, each branch corresponding to at least one defined action, wherein each branch comprises a plurality of successive branches, each successive branch corresponding to the at least one defined action; (b) providing a conditioned environment sensitive to the agent; (c) obtaining data from response of the agent to the conditioned environment; (d) extracting features from the obtained data; (e) selecting a branch from the decision tree corresponding to the features; (f) performing on the features the at least one defined action corresponding to the branch; (g) producing a classification of the agent; (h) iteratively repeating steps of (d)-(g) until the agent is discriminated, and (i) storing the classification of the agent for use.

Since the claimed invention involves mathematical algorithm, which is a judicial exception, the following analysis of facts of this particular patent application follows the rationale suggested in MPEP 2106.IV.C.2.

In the instant method claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56, there is no physical transformation by the claimed invention because using a predictive mathematical model to classify a test sample is not a physical transformation.

Since the claimed inventions, claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56, are a method, the following analysis of facts of this particular patent application follows the rationale suggested in Office's guidance to examiners under the Memorandum "Clarification of 'processes' under 35 USC § 101", published May 15, 2008, available online www.uspto.gov/web/patents/memorandum.htm

Paragraph three:

"Based on Supreme Court precedent¹ and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing.² If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and should be rejected as being directed to nonstatutory subject matter."

The instant method claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 are not tied to another statutory class (such as a particular apparatus) either explicitly or inherently. Nominal or token recitations will not suffice, e.g. displaying, inputting, obtaining, etc. See *ex parte Langemyr*; Appeal 2008-1495, decided May 28, 2008. The applicants are cautioned against introduction of new matter in an amendment.

Since the instant method claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56, do not provide a physical transformation, the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final

result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 1, 4, 6, 8-10, 13, 14, 28, 31, 33-37, 48, 51 and 53-56 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of discriminating an agent, to produce a real-world result. The last step of the claims includes storing the classification of the agent for use, the result of the invention is a set of data, such as a classification that is stored, which, in itself, is not tangible. There is no indication that the classification data may be accessible to a user. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Response to Arguments

Applicant's arguments filed 19 June 2008 have been fully considered but they are not persuasive.

Applicants argue that storing a classification or class for use will provide a tangible result to the invention.

Applicants arguments are not persuasive.

There is no guarantee that stored classifications or classes of agents, i.e. stored data, will be accessible to a user. The data may be stored and only accessible to another computer. There is no tangible result.

Claim Rejections - 35 USC § 103

This rejection is maintained and reiterated from the previous office action, mailed 19 March 2008.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6, 8-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wax (CH2847 IEEE, 1990, 2157-2160) in view of Li et al. (US 6,406,840) and further in view of Whitney (US Pat. Pub. 2002/0159642).

The claims are drawn to a method of A method for discriminating an agent, comprising the steps of: (a) constructing a decision tree having a plurality of branches, each branch corresponding to at least one defined action, wherein each branch comprises a plurality of successive branches, each successive branch corresponding to the at least one defined action; (b) providing a conditioned environment sensitive to the agent; (c) obtaining data from response of the agent to the conditioned environment; (d) extracting features from the obtained data; (e) selecting a branch from the decision tree corresponding to the features; (f) performing on the features the at least one defined action corresponding to the branch; (g) producing a classification of the agent; (h) iteratively repeating steps of (d)-(g) until the agent is discriminated, and (i) storing the classification of the agent for use.

Regarding claim 1, Wax shows a method of constructing a decision tree of structured classifiers, wherein classification is carried out by a sequence of test determined by the path in the tree that the object (agent) to be classified transverses and the path taken from each node depends on the test result obtained at that node (i.e.

leaf), then when a terminal leaf is reached the object is assigned the class-tag associated with that leaf, (see page 2157, right column, paragraphs 4 and 5; Figure 1).

Wax does not show steps b)-d), f) and h), providing a conditioned environment sensitive to the agent, obtaining data from response of the agent to the conditioned environment, extracting features from the obtained data, performing on the features at least one defined action corresponding to the branch and repeating steps d)-g) until the agent is discriminated.

Li et al. shows cell arrays for conducting comparative cell-based analyses, wherein a biological or chemical agent are tested against numerous cell types, (see column 12, line 45 - column 13, line 8; column 16, lines 7-30; Figure 1).

Wax and Li et al. do not show steps d), f) and h), extracting features from the obtained data; performing on the features at least one defined action corresponding to the branch, and iteratively repeating steps of (d)-(g) until the agent is discriminated.

Whitney shows a method for designing algorithms that allow fast retrieval, classification, analysis and processing of data, (see paragraphs [0007-9]; Figure 1 and 5). Whitney shows automated pattern recognition process that may be applied across diverse data types and used in virtually any field, (paragraph [0051]) wherein feature selection performed from any data object or data set, (paragraph [0053-54], [0081[0145]; Figures 7, 8, 14 and 20A-20E). Whitney shows the selection and training of a classifier in order to assign a feature vector extracted form a data object to a particular class, (see [0158]), wherein different classifiers can be used or refined with respect to the feature to classify a data object to a respective class, (see paragraphs

[0068-0076]). Whitney shows a repeated feedback path that allows continually modifying the process and if new feature selection is required, to correctly classify the data object until a stopping condition is met, (see paragraphs [0077-78], [0083-0085]; Figures 1-5).

Regarding claim 4, Li et al. shows testing of a biological agent, (see column 12, lines 26-44).

Regarding claim 6, Wax shows a best split rule of nodes according to the minimum description length principle, (see 2159, left column, paragraphs 1-4).

Regarding claims 8-10, Li et al. shows providing data pertaining to possible viral pathogens associated particular diseases and selecting cell types and exposing selected cell types to a conditioned environment, (see column 12, line 9 - column 13, line 8; column 16, lines 7-30; Figure 1).

Regarding claims 13 and 14, Whitney shows selecting a feature extraction algorithm and classification method (classifier) from a library of algorithms, (see paragraph [0140]), and a plurality of classifications methods, wherein the classifier is applied to the extracted data feature to produce a classification, (see paragraph [0162-0163]).

It would be obvious to one skilled in the arts to modify the method of tree structured classifiers by Wax with the method cellular assays with agent by Li et al. and the methods of feature selection and classification by Whitney because the agent specific data, feature selection of said data and subsequent classification of said

features would be easily implemented in the splitting and pruning rules derived by Wax to better classify an agent of interest, (see Wax, page 2160, last two paragraphs).

Response to Arguments

Applicant's arguments filed 19 June 2008 have been fully considered but they are not persuasive.

Applicants argue that Wax, Li and Whitney taken alone or in combination, disclose, teach or suggest the invention, including the steps of 1) constructing a decision tree having a plurality of branches, each branch corresponding to at least one defined action, 2) performing on the features the at least one defined action corresponding to the branch, and 3) iteratively repeating steps of d-g until the agent is discriminated. Applicants argue there is no motivation, no reasonable expectation of success and the combined art do not teach all the elements of the invention.

Applicant's arguments are not persuasive.

Wax shows a branched decision tree with each branch as a test and each node as a result of said test, (page 2157, right column, paragraphs 4 and 5; Figure 1). It would be obvious that a test may be an experiment or "defined action".

Li et al. shows cell arrays for conducting comparative cell-based analyses, wherein a biological or chemical agent are tested against numerous cell types, (see column 12, line 45 - column 13, line 8; column 16, lines 7-30; Figure 1). It would be obvious that a test may include analyzing the effects of an agent on cell types.

Whitney shows a repeated feedback path that allows continually modifying the process and if new feature selection is required, to correctly classify the data object until a stopping condition is met, (see paragraphs [0077-78], [0083-0085]; Figures 1-5).

All the elements of the claims are provided within the cited art. KSR International Co. v. Teleflex Inc., provides a rationale wherein a claim would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation but of ordinary skill and common sense. Motivation is not required to make a *prima facie* case of obviousness. It is enough to have a likelihood of success with known technical features in the prior art. It would be obvious to try to place method cellular assays with agent by Li et al. as the branches of the decision tree by Wax and combine the reiteration of steps to result in a classification as provided in Whitney et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shubo (Joe) Zhou/
Primary Examiner, Art Unit 1631

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631